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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/701,626 | 12/01/2000 | Elisabeth A. Raleigh | NEB-165-PUS | 8938 |

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[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1634

DATE MAILED: 06/19/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------|----------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/701,626 | RALEIGH ET AL. |
| | Examiner | Art Unit |
| | Arun Chakrabarti | 1634 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 April 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 15 and 16 is/are withdrawn from consideration.
- 5) Claim(s) 7-14 and 17 is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7</u> . | 6) <input checked="" type="checkbox"/> Other: <i>Detailed Action</i> . |

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DETAILED ACTION

Specification

1. Applicant's election of Group I, corresponding to claims 1-14 and 17, in Paper NO: 9 is hereby acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2, the phrase "such as" in several places of the claim renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Regarding claim 2, the phrase "especially" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

The term "small molecule" and "narrow" in claim 2 are relative terms which render the claim indefinite. The terms "small molecule" and "narrow" are not defined by the claim, the

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specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 102 (b) as being anticipated by Silver et al. (U.S. Patent 4,994,370) (February 19, 1991).

Silver et al teaches a method for the cloning of intact, diversity-selected genes from within gene cassettes, the method comprising the steps of:

- a) identifying repeat DNA sequences which flank gene cassettes (Figure 4, step 1);
- b) hybridizing oligonucleotides to the repeated sequences which flank the gene cassettes and amplifying the sequences to provide DNA fragments which contain genes from within the cassettes (Figure 4, steps II and III);
- c) inherently ligating the DNA fragments into a vector (Column 7, lines 13-16 and Column 8, lines 26-28);

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d) transforming the vector into an appropriate strain (Column 8, lines 26-28).

Silver et al inherently teaches a method, wherein the diversity-selected genes are selected from transporters of small molecules (Figures 1-4 and Column 6, lines 61-68).

Silver et al teaches a method, wherein the oligonucleotides contain recognition sites which permit directional cloning (Column 7, lines 13-16).

Silver et al inherently teaches a method, wherein the DNA fragments are ligated into the vector in an orientation that enables expression (Column 8, lines 26-28).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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7. Claim 3 is rejected under 35 U.S.C. 103 (a) over Xu (U.S. Patent 5,492,823) (February 20, 1996) in view of Silver et al. (U.S. Patent 4,994,370) (February 19, 1991).

Xu teaches a method of cloning the diversity-selected genes comprising restriction-endonuclease genes (Abstract and Examples 1-5 and Figure 3).

Xu does not teach a method for cloning according to claims 1-2.

Silver et al. teach a method for cloning according to claims 1-2 as described above.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method of cloning of Silver et al. in the method of cloning the diversity-selected genes comprising restriction-endonuclease genes of Xu since Silver et al. state, “While standard cloning techniques could be used to obtain the same results, the “inside-out” PCR method is substantially superior, yielding purified “junction” fragment DNA in a single day, compared to a few weeks for standard cloning (Column 9, lines 36-40)”. By employing scientific reasoning, an ordinary practitioner would have been motivated to substitute and combine the method of cloning of Silver et al. in the method of cloning the diversity-selected genes comprising restriction-endonuclease genes of Xu in order to achieve the express advantages, as noted by Silver et al., of a cloning technique which is substantially superior, yielding purified “junction” fragment DNA in a single day, compared to a few weeks for standard cloning.

8. Claim 4 is rejected under 35 U.S.C. 103 (a) over Stein et al. (U.S. Patent 5,491,060) (February 13, 1996) in view of Silver et al. (U.S. Patent 4,994,370) (February 19, 1991).

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Stein et al. teaches a method of cloning the diversity-selected genes comprising methyltransferase genes (Abstract and Column 2, lines 15-44 and Example).

Stein et al. does not teach a method for cloning according to claims 1-2.

Silver et al. teach a method for cloning according to claims 1-2 as described above.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method of cloning of Silver et al. in the method of cloning the diversity-selected genes comprising methyltarnsferase genes of Stein et al. since Silver et al. state, “While standard cloning techniques could be used to obtain the same results, the “inside-out” PCR method is substantially superior, yielding purified “junction” fragment DNA in a single day, compared to a few weeks for standard cloning (Column 9, lines 36-40)”. By employing scientific reasoning, an ordinary practitioner would have been motivated to substitute and combine the method of cloning of Silver et al. in the method of cloning the diversity-selected genes comprising methyltransferase genes of Stein et al. in order to achieve the express advantages, as noted by Silver et al., of a cloning technique which is substantially superior, yielding purified “junction” fragment DNA in a single day, compared to a few weeks for standard cloning.

Allowable Subject Matter

9. Claims 7-14, and 17 are allowed because no prior art of record either teach or suggest the SEQ ID Numbers disclosed in the claims.

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Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

**Arun Chakrabarti
Patent Examiner
Art Unit 1634**

June 4, 2002


**W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600**